HFI-35 (no purging needed)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m40960

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

AUG 25 2000

Michael S. Poirier
President and Chief Executive Officer
Qualigen, Inc.
2042 Corte Del Nogal
Carlsbad, California 92009

Dear Mr. Poirier:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed several press releases and some Internet promotional materials for Qualigen, Inc.'s (Qualigen's) FastPack™ Total PSA Assay. The assay is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act.

FDA granted the company marketing clearance for the device after its review of Qualigen's (then Qualysis) submission, k994419. The device was cleared with the following Indications for Use language: "The FastPack™ PSA Immunoassay is a paramagnetic particle chemiluminescence immunoassay for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum. The FastPack™ PSA Immunoassay is indicated as an aid in the management of patients with prostate cancer. The FastPack™ PSA Immunoassay is designed for use with the FastPack™ Analyzer System."

A press release issued by the company and dated July 10, 2000 makes several inappropriate claims for the device. The press release states, "The FastPack System is the first system to be granted marketing clearance by the FDA. . .*designed specifically to perform a broad menu of quantitative immunoassay tests in physician offices and small laboratories.*" The press release states that "the first test available will be *total prostate specific antigen (Total PSA) for the diagnosis of prostate cancer,* which also has been cleared for marketing in the U.S. by the FDA." The press release further states, " With the FastPack System, physicians are able to obtain laboratory quality test results in less than 15 minutes, *thereby eliminating the need to send a patient's blood sample to a commercial or hospital laboratory* and wait several days for the results. In addition to the Total PSA test, two other prostate cancer related *diagnostic tests,* free prostate specific antigen (PSA) and testosterone, are scheduled for introduction following FDA marketing clearance later this year." You are quoted as saying, "We are very excited about the potential market opportunity for the FastPack System, first for prostate cancer and soon after with up to 25 additional tests *to diagnose multiple other serious medical conditions*, such as other types of cancer . . ." (Emphases added.)

FDA objects to these representations of the company's product. The claim for use as a diagnostic device rather than as an aid in the management of patients who have already been diagnosed with prostate cancer is inconsistent with the cleared intended use as quoted above.

The agency's regulations at 21 CFR 801.4 provide that the "intended use" of a device refers to the objective intent of the persons legally responsible for the labeling of a device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. Objective intent may be shown by, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

The Office of Device Evaluation (ODE) has advised us that the device was not cleared in this country to be used as a point-of-care device or for use in physicians' offices. While your press release makes explicit claims for obtaining results in less than 15 minutes and without sending a blood sample to a commercial or hospital laboratory and without the presence of trained laboratory technicians, ODE has stated that the product was cleared as a prescription device intended for use in a hospital laboratory where trained technicians are operating it. The Center would require the company to submit further data to support claims of safe and effective use outside a hospital laboratory setting.

Finally, the word, "Approved" across the website picture of the clearance letter is misleading. The FastPack was cleared through the premarket notification process and was not approved through the premarket approval application procedures.

The FastPack is misbranded and adulterated within the meaning of 502(o) and 501(f)(1)(B), respectively, of the Act. It is misbranded because the company has not submitted to FDA the required notice and other information respecting the device as required by section 510(k) of the Act. It is adulterated because, as promoted, it is a class III device without either an approved premarket approval application as required by section 515 or an approved investigational device exemption, as provided by section 520(g) of the Act.
This letter is not intended to be an all-inclusive list of deficiencies associated with Qualigen's devices. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter may also be reflected in other promotion and advertising materials used by your company. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps that you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office, Food and Drug

Administration (HFR-PA240), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92715..

Sincerely yours,

Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health